

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME voting recommendations on the Medical Devices Regulations revision

In relation to the European Parliament Public Health Committee [draft report](#) by MEP Oliver Schenk and amendments tabled for the Proposal for a Regulation to simplify rules on medical and in vitro diagnostic devices,

- CPME¹ reminds that patient safety and ethics shall not be subject to negotiation, and recommends the following:
 - **To support amendments 166, 167, 168, 169, 785, 786, 787 and 788:** CPME strongly supports maintaining medical devices under the comprehensive requirements for high-risk AI under the AI Act.
 - **To support amendments 34, 35 and 36** to protect patients by ensuring comprehensive regulatory safeguards, effective compensation and accountability and to avoid dangerous simplifications that could cause harm to patients.
 - **To support amendment 1** which underlines that simplification should not weaken clinical evidence.
 - **To support amendment 9** which proposes deletion of recital 39 on equivalence flexibility.
 - **To reject amendments 6 and 31** that propose English-only Instructions for Use (IFU) for professional-use devices. CPME points out that Electronic Instructions for Use shall be made available in all EU languages.
 - **To reject amendment 14**, we defend that a new category of niche devices shall not be created, but instead be adequately integrated in the current category of orphan devices.
 - **To reject amendment 92** that removes only class III implantable devices from the equivalence route entirely. CPME is against the relaxation of clinical evidence requirements for all high-risk devices (class III), we emphasize that direct clinical

¹ The CPME proposed amendments to the Medical Devices Regulation Revision may be accessed [here](#).

Also, the statement on medical devices may be accessed [here](#) and the CPME statement on medical devices – electronic instructions for use may be accessed [here](#).

evidence from the manufacturer is essential to ensure patient safety and maintain public trust. All class III on high risk devices shall be removed from the equivalence route.

- To **support amendment 128**, but also to add to include also a provision that the software used for the electronic instructions shall comply with Regulation 2016/679, and profiling of patients shall be forbidden.